

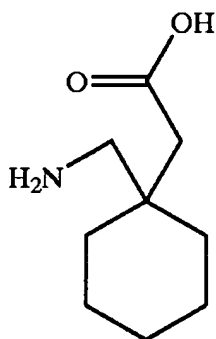
IN THE CLAIMS:

The text of all pending claims, (including withdrawn claims) is set forth below. Cancelled and not entered claims are indicated with claim number and status only. The claims as listed below show added text with underlining and deleted text with ~~striketrough~~. When strikethrough cannot easily be perceived, or when five or fewer characters are deleted, [[double brackets]] are used to show the deletion. The status of each claim is indicated with one of (original), (currently amended), (cancelled), (withdrawn), (new), (previously presented), or (not entered).

Please AMEND claims 1, 6, 10, 14, and 19, and CANCEL claim 13 without prejudice or disclaimer in accordance with the following:

1. (Currently amended) A process for the preparation of Gabapentin of the formula

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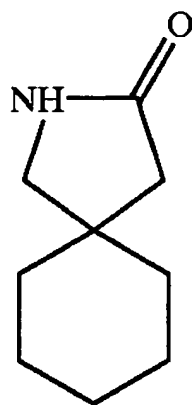
gabapentin

which ~~comprises~~ consists essentially of:

- (i) preparing an aqueous solution of Gabapentin hydrochloride in water in a ratio of one part by weight of the Gabapentin hydrochloride to 0.5 to 3 parts by weight of the water;
- (ii) preparing an aqueous solution of an alkali metal base in a concentration in the range of 40-50% w/w;
- (iii) adding 0.08 to 0.3 parts by weight of the solution obtained in step (ii) to 1.5 to 4 parts by weight of the solution obtained in step (i) at a temperature in the range of 0 to 20 degree C to form a resulting solution;
- (iv) heating the resulting solution gradually to a temperature in the range of ~~50-90~~ 60-90 degree C;

- (v) gradually cooling the resulting solution to a temperature in the range of 0 to 15 degree C to obtain a precipitate;
 - (vi) aging the precipitate for a period of time in the range of 0.5 hrs to 8 hrs at a temperature in the range of 0 to 15 degree C;
 - (vii) separating the precipitate from its mother liquor by conventional methods; and
 - (viii) recrystallising the precipitate from a mixture of isopropyl alcohol (IPA), methanol & water in a ratio ranging from 4.54-19.64 : 3.88-15.64 : 1 (v/v) to get Gabapentin of over 99.5% purity and another mother liquor, wherein the Gabapentin has a chloride content of 100 ppm or less.
2. (Previously presented) The process as claimed in claim 1, wherein the amount of the gabapentin hydrochloride and the water used in step (i) is in the ratio of 0.5 to 2.5 parts of water to 1 part of the Gabapentin hydrochloride or in the ratio of 1.5 to 2.5 parts of the water to 1 part of the Gabapentin hydrochloride.
3. (Previously presented) The process as claimed in claim 1, wherein the alkali metal base used in step (ii) is sodium hydroxide, or potassium hydroxide.
4. (Previously presented) The process as claimed in claim 1, wherein the solution of the alkali metal base used is in a concentration in the range of 40-50% w/w in water or in the concentration in the range of 45-50% w/w in water.
5. (Previously presented) The process as claimed in claim 1, wherein the temperature employed in step (iii) is 10 to 20 deg C, or 10 to 15 deg C.
6. (Currently amended) The process as claimed in claim 1, wherein the temperature employed in step (iv) used is in the range of ~~50-60~~ to 75 deg C or in the range of 60 to 70 deg C.
7. (Previously presented) The process as claimed in claim 1, wherein the temperature employed in step (v) is in the range of 5 to 15 degree C or in the range of 5 to 10 degree C.

8. (Previously presented) The process as claimed in claim 1, wherein the time employed for aging the precipitate in step (vi) is between 0.5 to 3 hrs or between 0.5 to 1 hr.
9. (Previously presented) The process as claimed in claim 1, wherein the separation of Gabapentin in step (vii) is effected by filtration or centrifugation.
10. (Currently amended) A process for the preparation of Gabalactam of the formula 3 represented by:

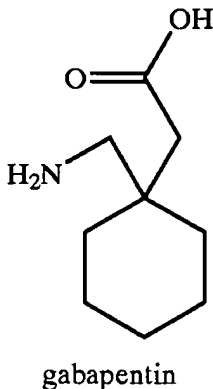


which ~~comprises~~consists essentially of:

- (i) preparing an aqueous solution of Gabapentin hydrochloride in water in a ratio of one part by weight of the Gabapentin hydrochloride to 0.5 to 3 parts by weight of the water;
- (ii) preparing an aqueous solution of an alkali metal base in a concentration in the range of 40-50% w/w;
- (iii) adding 0.08 to 0.3 parts by weight of the solution obtained in step (ii) to 1.5 to 4 parts by weight of the solution obtained in step (i) at a temperature in the range of 0 to 20 degree C to form a resulting solution;
- (iv) heating the resulting solution gradually to a temperature in the range of ~~50-90~~60-90 degree C;
- (v) gradually cooling the resulting solution to a temperature in the range of 0 to 15 degree C to obtain a precipitate;
- (vi) aging the precipitate for a period of time in the range of 0.5 hrs to 8 hrs at a temperature in the range of 0 to 15 degree C;
- (vii) separating the precipitate from its mother liquor by conventional methods;

- (viii) recrystallising the precipitate from a mixture of isopropyl alcohol (IPA), methanol & water in a ratio ranging from 4.54-19.64 : 3.88-15.64 : 1 (v/v) to get Gabapentin of over 99.5% purity, wherein the Gabapentin has a chloride content of 100 ppm or less, and another mother liquor;
 - (ix) treating the mother liquors from steps (vii) & (viii) with aqueous sodium hydroxide in a concentration in the range of 5 to 20% at a temperature in the range of 80 to 100 degree C; and
 - (x) recovering the Gabalactam by extraction with organic solvents.
11. (Previously presented) The process as claimed in claim 10, wherein in step (ix), the concentration of sodium hydroxide ranges from 10 to 20%, and the temperature ranges from 80 to 85 degree C.
12. (Previously presented) The process as claimed in claim 10, wherein in step (x), the recovery of Gabalactam is effected by extraction with organic solvents selected from the group consisting of toluene, ethylene dichloride, methylene dichloride and hexane.
13. (Canceled)
14. (Currently amended) The process as claimed in claim 13¹, wherein the chloride content is 40 to 95 ppm.
15. (Previously presented) The process as claimed in claim 14, wherein the chloride content is 40 to 90 ppm.
16. (Previously presented) The process as claimed in claim 15, wherein the chloride content is 40 to 70 ppm.
17. (Previously presented) The process as claimed in claim 16, wherein the chloride content is 40 to 60 ppm.
18. (Previously presented) The process as claimed in claim 17, wherein the chloride content is 40 to 50 ppm.

19. (Currently amended) A process for the preparation of Gabapentin of the formula
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which ~~comprises~~consists essentially of:

- (i) providing an aqueous solution of Gabapentin hydrochloride having a ratio of parts by weight of Gabapentin hydrochloride to parts by weight of water from 0.5 to 3;
- (ii) at a temperature in the range from 0 to 20 degree C, adding 0.08 to 0.3 parts by weight of an aqueous alkali metal base solution at a concentration from 40 to 50% w/w to 1.5 to 4 parts by weight of the aqueous solution of the Gabapentin hydrochloride to form a resulting solution;
- (iii) heating the resulting solution gradually to a temperature from 60
~~65~~ to 90 degree C;
- (iv) then, cooling the resulting solution gradually to a temperature from 0 to 15 degree C to obtain a precipitate;
- (v) maintaining the precipitate in the solution at the temperature from 0 to 15 degree C for a time from 0.5 hrs to 8 hrs;
- (vi) separating the precipitate from its mother liquor; and
- (vii) recrystallising the precipitate from a solvent mixture containing isopropyl alcohol (IPA), methanol & water in a ratio ranging from 4.54-19.64 : 3.88-15.64 : 1 (v/v) to obtain Gabapentin of at least 99.5% purity and having a chloride content of 100 ppm or less, and a lactam content of 0.05% or less,

wherein the process excludes an ion exchange conversion of Gabapentin hydrochloride, and

wherein the Gabapentin has a chloride content of 100 ppm or less.

- 20.** (Previously presented) The process of claim 19, wherein the chloride content is from 40 to 50 ppm and the lactam content is from 0.01 to 0.045%.

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